

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

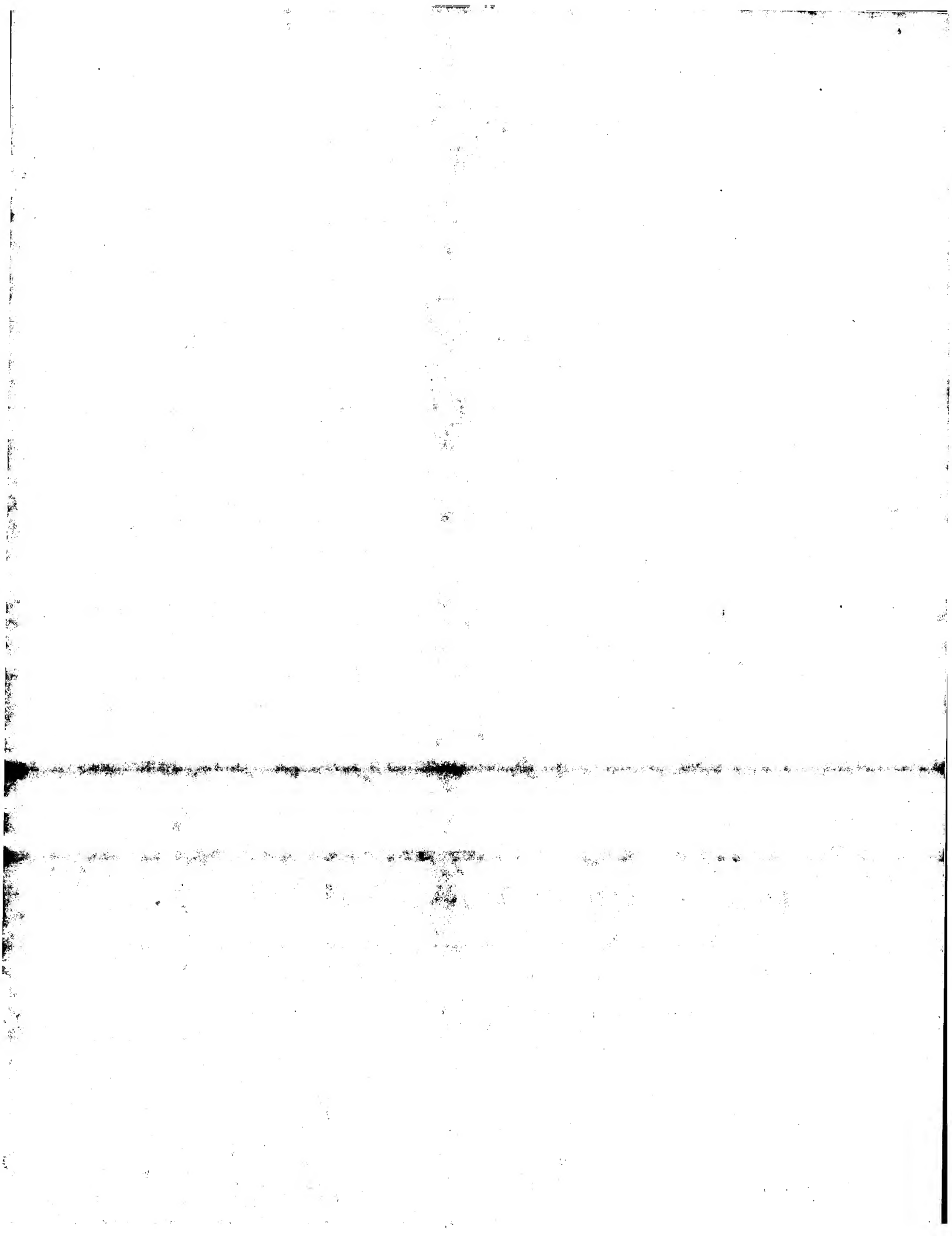
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

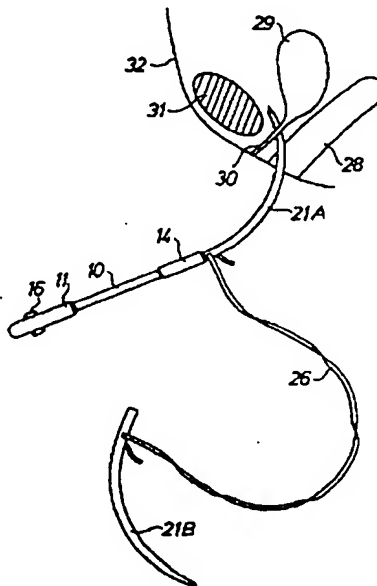
IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**





(72) CLAREN, Jan, SE
(72) ULMSTEN, Ulf, SE
(71) MEDSCAND AB, SE
(71) KB ULMUS, SE
(51) Int.Cl.⁶ A61B 17/42
(30) 1994/08/30 (9402872-7) SE
(54) INSTRUMENT CHIRURGICAL POUR LE TRAITEMENT DE
L'INCONTINENCE URINAIRE FEMININE
(54) SURGICAL INSTRUMENT FOR TREATING FEMALE
URINARY INCONTINENCE



(57) La présente invention concerne un instrument chirurgical destiné au traitement de l'incontinence urinaire chez la femme. L'instrument est constitué d'une queue (10) munie d'une poignée (11) à l'une de ses extrémités et deux éléments en forme d'aiguille incurvée (21A, 21B), raccordés par l'une de leurs extrémités à une extrémité d'un ruban destiné à être implanté dans le corps. Ces éléments, qui peuvent être raccordés un à la fois avec l'autre extrémité de la queue de façon à constituer une partie extrême incurvée de la queue, sont prévus pour être introduits par le vagin dans le corps, chaque élément étant dimensionné pour être disposé au

(57) The invention relates to a surgical instrument and a method for treating female urinary incontinence. The instrument comprises a shank (10) having a handle (11) at one end thereof, and two curved needle-like elements (21A, 21B) which are connected at one end thereof each with one end of a tape (26) intended to be implanted into the body. These elements can be connected one at a time with the shank at the other end thereof to form a curved end portion of the shank and are intended to be passed into the body via the vagina, each element being dimensioned to extend from the inside of the vaginal wall over the back of the pubic bone to the outside of the



OPIC
OFFICE DE LA PROPRIÉTÉ
INTELLECTUELLE DU CANADA



CIPPO
CANADIAN INTELLECTUAL
PROPERTY OFFICE

(21) (A1) 2,198,778
(86) 1995/08/28
(87) 1996/03/07

dessus de la face arrière de l'os pubien, de l'intérieur à l'extérieur de la paroi vaginale. Le procédé consiste à introduire par le vagin (28) le ruban (26) dans le corps, d'abord sur l'une des extrémités puis sur l'autre extrémité, de part et d'autre de l'urètre (30) de façon à entourer la paroi vaginale d'une boucle, puis à faire passer le ruban au dessus du pubis (31) et au travers de la paroi abdominale (32), et enfin à serrer le ruban. Les extrémités du ruban sont ensuite coupées au niveau de la paroi abdominale, le ruban restant dans le corps.

abdominal wall. When practising the method the tape (26) is passed into the body via the vagina (28) first at one end and then at the other end at one side and the other, respectively, of the urethra (30) to form a loop around the vaginal wall. The tape is extended over the pubis (31) and through the abdominal wall (32) and is tightened. Then, the tape ends are cut at the abdominal wall, and the tape is left in the body.



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

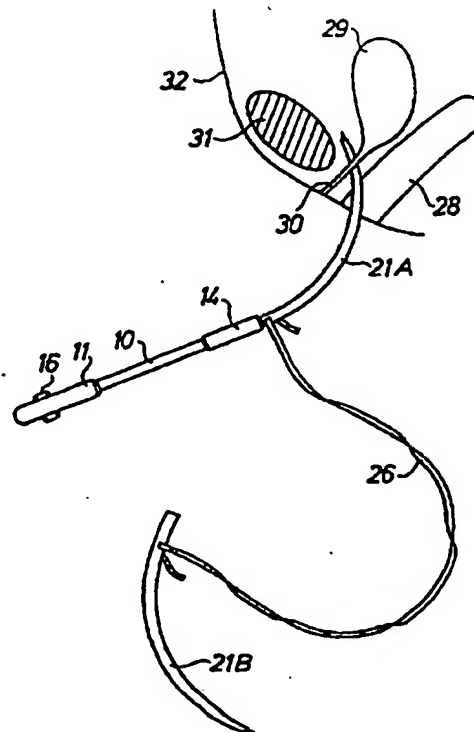
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: A61B 17/04, 17/42		A1	(11) International Publication Number: WO 96/06567
			(43) International Publication Date: 7 March 1996 (07.03.96)
(21) International Application Number: PCT/SE95/00964		(81) Designated States: AU, CA, CN, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 28 August 1995 (28.08.95)		Published With international search report. With amended claims. 2198778	
(30) Priority Data: 9402872-7 30 August 1994 (30.08.94) SE			
(71) Applicants (for all designated States except US): MEDSCAND AB [SE/SE]; P.O. Box 20047, S-200 74 Malmö (SE). KB ULMUS [SE/SE]; P.O. Box 60201, S-216 09 Malmö (SE).			
(72) Inventors; and (75) Inventors/Applicants (for US only): CLARÉN, Jan [SE/SE]; Protokollgränden 38, S-226 47 Lund (SE). ULMSTEN, Ulf [SE/SE]; Riddvägen 18 D, S-182 35 Danderyd (SE).			
(74) Agents: STRÖM, Torbjörn et al.; Ström & Gulliksson AB, P.O. Box 4188, S-203 13 Malmö (SE).			

(54) Title: SURGICAL INSTRUMENT FOR TREATING FEMALE URINARY INCONTINENCE

(57) Abstract

The invention relates to a surgical instrument and a method for treating female urinary incontinence. The instrument comprises a shank (10) having a handle (11) at one end thereof, and two curved needle-like elements (21A, 21B) which are connected at one end thereof each with one end of a tape (26) intended to be implanted into the body. These elements can be connected one at a time with the shank at the other end thereof to form a curved end portion of the shank and are intended to be passed into the body via the vagina, each element being dimensioned to extend from the inside of the vaginal wall over the back of the pubic bone to the outside of the abdominal wall. When practising the method the tape (26) is passed into the body via the vagina (28) first at one end and then at the other end at one side and the other, respectively, of the urethra (30) to form a loop around the vaginal wall. The tape is extended over the pubis (31) and through the abdominal wall (32) and is tightened. Then, the tape ends are cut at the abdominal wall, and the tape is left in the body.



2198778

CLAIMS

1. Surgical instrument for treating female urinary incontinence, comprising a shank (10) having a handle (11) at one end thereof and a curved portion (21) at the other end thereof said portion being intended to be passed into the body via the vagina, characterized in that two curved needle-like elements (21A, 21B) which are each connected at one end thereof to one end and the other, respectively, of a tape (26) to be permanently implanted into the body as a loop around urethra, are constructed to be connected one at the time with the shank (10) to form said curved portion each element being dimensioned to extend from the inside surface of the vaginal wall over the back of the pubic bone to the outside of the abdominal wall.

2. Instrument as in claim 1 characterized in that the shank (10) has a screw coupling (18, 23) for attachment of the element (21A, 21B) to the shank (10).

3. Instrument as in claim 2 characterized in that the screw coupling comprises a shaft (15) rotatably mounted in the shank (10) and having an operating knob (16) at one end of the shaft said knob being available at the handle end of the shank, and a threaded portion (18) at the other end of the shaft for screw engagement with the element (21A, 21B).

4. Instrument as in any of claims 1 to 3 characterized in that the shaft (10) has a sleeve portion (14) at said other end thereof to receive therein an end portion of the needle-like element (21A, 21B) at said one end of the element.

AMENDED SHEET

2198778

5. Instrument as in any of claims 1 to 4
characterized in that the handle (11)
comprises two wings (12) projecting diametrically from the
shank (10).

5 6. Instrument as in claim 5
characterized in that the shank (10) and the
needle-like elements (21A, 21B) have mutually co-operating
means (20, 25) for positioning the respective elements on
the shank (10) at right angles to the plane of the wings
10 (12).

7. Instrument as in any of claims 1 to 6
characterized in that the shank (10) is
intended for use several times and consists of a material
that can be autoclaved, the needle-like elements (21A, 21B)
15 being intended for a single use and consist of plastics
material, stainless steel or similar material.

8. Instrument as in claim 7
characterized in that the tape (26) is
attached to the associated element (21A, 21B) by the tape
20 ends being glued or welded to the elements or being baked
into the plastics material of the elements.

9. Instrument as in claim 7
characterized in that the tape ends are passed
through an eye (27) in the associated element (21A, 21B).

25 10. Instrument as in any of claims 1 to 9
characterized in that the needle-like elements
are curved over substantially a quarter of a circle.

11. Instrument as in any of claims 1 to 10
characterized in that the elements (21A, 21B)
30 taper towards the other, free end thereof.

12. Instrument as in claim 11
characterized in that said other end is
pointed.

13. Instrument as in claim 11
35 characterized in that said other end is blunt.

AMENDED SHEET

2198778

14. Instrument as in any of claims 1 to 13
c h a r a c t e r i z e d in that the tape (26) is
perforated for growth of fibroblasts thereinto.

15. Instrument as in claim 14
5 c h a r a c t e r i z e d in that the tape (26) comprises
a woven tape.

16. Instrument as in claims 14 or 15
c h a r a c t e r i z e d in that the tape is coated with
a fibroblast stimulating material.

10 17. (Amended). Method for treating female urinary
incontinence wherein a tape (26) is passed into the body
and is implanted at each side of the urethra between the
vaginal wall and the abdominal wall extending over the
pubic bone, c h a r a c t e r i z e d in that the tape is
15 passed into the body via the vagina first at one end
thereof and then at the other end thereof at one side and
the other, respectively, of urethra to form a loop around
urethra, and that the tape is tightened.

AMENDED SHEET

TITLE OF THE INVENTION: Surgical instrument for treating
female urinary incontinence

The invention relates to a surgical instrument and a method for treating female urinary incontinence, i.e. incapacity of controlling the discharge of urine.

Urinary incontinence may be caused by a defect function
5 in the tissue or ligaments connecting the vaginal wall with the pelvic muscles and pubic bone.

US-A-5 112 344 describes a method for treating female urinary incontinence without the necessity of opening the abdomen, which would require hospital care for may be four
10 days. In this method a tape is passed into the body at each side of the urethra and is implanted between the vaginal wall and the abdominal wall extending over the pubis. The tape is tightened in order to bring the vaginal wall and the urethra into correct position in relation to the pubis and
15 is left in the body in order that fibrous tissue shall develop around the tape, said fibrous tissue functioning as a supporting ligament in the soft tissue. The tape is removed from the body when such fibrous tissue has developed, which takes about two months.

20 A surgical instrument of special construction is also proposed for use with this method, comprising a shank having a handle at one end thereof and a curved portion at the other end thereof said portion being intended to be passed into the body via the vagina.

25 The result obtained by such surgery is not always satisfactory due to the fact that fibrous tissue will not develop sufficiently since the soft tissue between the vaginal wall and the abdominal wall is in bad condition.

The object of the invention is to provide improved and simplified surgery with a considerably improved prognosis

with regard to restoration of the urinary continence, and for this purpose the invention provides a surgical instrument of the kind referred to above having the characterizing features of claim 1.

5 The invention also provides a method for treatment of female urinary incontinence in accordance with claim 17. Also in this method a tape is passed into the tissue between the vaginal wall and the abdominal wall but the tape is left permanently in the body to provide itself, as an artificial
10 ligament, the reinforcement of the tissue required in order to restore the urinary continence, or to provide said reinforcement by the development of fibrous tissue.

The invention will be explained in more detail with reference to the accompanying drawings which disclose the
15 surgical instrument according to the invention as well as several surgical steps when practising the method of the invention using said surgical instrument.

In the drawings

20 FIG. 1 is a side view of the surgical instrument in one embodiment thereof,

FIG. 2 is a plan view of the surgical instrument,

FIG. 3 is an enlarged fragmentary axial cross sectional view of a coupling of the instrument for attaching an exchangeable part thereof,

25 FIGS. 4 to 10 illustrate diagrammatically several surgical steps of the method according to the invention, and

FIG. 11 in the same way illustrates the final step of the method.

30 The surgical instrument comprises a cylindrical tubular shank 10 having at one end thereof a handle 11 which forms two in opposite directions in a common plane projecting wings 12 and an opening 13. At the other end of the shank there is a socket 14 which is partly passed onto
35 the shank and is soldered or brazed to the shank, a portion of the socket projecting from the shank at said other end

thereof. A cylindrical shaft 15 is rotatably mounted in the shank and can be rotated manually by means of a knob 16 axially knurled at the outside surface thereof, which is mounted to one end of the shaft and is received by opening 13. The other end of the shaft forms a cylindrical portion 17 of smaller outside diameter than the shaft, which joins a portion 18 having external threads, a smooth end portion 19 of further reduced diameter joining the threaded portion 18, end portion 19 forming a guide pin at said other end of the shaft. Portions 18 and 19 are received in the portion of socket 14 projecting from the shank, and also a shoulder 20 projecting from the shank is received in said portion.

The surgical instrument as described so far is intended to be used several times and therefore should consist of a material which can be sterilized by autoclaving, e.g. of stainless steel.

The surgical instrument also includes an exchangeable and disposable element 21 which will be termed needle. It is attached to the shank at a straight portion at one end of the needle and extends over substantially a quarter of a circle to the other, free end thereof in order to follow substantially the profile of the pubis between the vagina and the abdominal wall. The needle has circular cross section and has a smooth, preferably polished outside surface. It tapers slightly towards the free end thereof where the needle forms a point 22 by being faceted but it can also be blunt-ended and have a transversely cut end. The practical use of the surgical instrument will show which embodiment is to be preferred. The disposable needle shall be made either of a tissue compatible plastics, such as polycarbonate, or of steel or a similar material.

For attachment of needle 21 to shank 10 the needle has at said one end thereof where the needle forms a straight portion to be received at said portion in socket 14, an axial blind hole extending from the end surface said hole having a threaded portion 23 and inwardly thereof a

narrower, cylindrical portion 24. Guide pin 19 is dimensioned to be guidingly received by said latter portion when the threaded portion 18 for attaching needle 21 to the rest of the surgical instrument is screwed into threaded portion 23 of the blind hole by rotating shaft 15 by manual rotation of knob 16, the end surfaces of the shank and the needle being pressed against each other. The needle should be oriented in a predetermined rotational position in relation to the shank; it should project at right angles to the plane of handle 16, and this rotational position is secured by shoulder 20 on the shank being received in a mating recess 25 in the outside surface of the needle.

Portion 23 of needle 21 instead of being threaded can be dimensioned such that the threaded portion 18 of shaft 15 cuts a thread in the plastics of the needle when being screwed thereinto.

When the two parts of the surgical instrument are screwed together in the manner described they form a rigid unit which can be controlled with great precision at handle 11 when it is used for surgery by applying the method of the invention.

When the method according to the invention is practised two needles 21A and 21B of the embodiment described shall be connected one at each end of a tape 26, Fig. 4. In the preferred embodiment the tape end is glued to the needle but the connection can be effected also by the tape being passed through an eye 27, Fig. 3, in the needle adjacent the end attached to the shank or by the tape end being connected by ultrasonic welding to the needle or being baked into the plastics material of the needle at injection molding thereof.

The tape should be a woven tape having apertures between weft and warp of the order of 0.1 mm in order that fibroblasts shall be able to grow into the tape for anchoring of the tape in surrounding tissue. A suitable material for the tape is polypropylene which also can be

coated with a fibroblast stimulating substance, e.g. an enamel matrix derivative. Preferably the tape has a width of 8 to 10 mm and a thickness of about 1 mm.

5 When the surgery for implanting the tape shall start one needle 21A is attached to shank 10, the other needle 21B hanging loosely in tape 26 as shown in Fig. 4.

10 In Figs. 4 to 11 the relevant parts of the female lower abdomen is disclosed diagrammatically, the vagina being designated 28, the urinary bladder 29, the urethra 30, the pubic bone 31, and the abdominal wall 32.

15 The first step of the surgery for implanting tape 26 is disclosed in Fig. 4 and comprises penetration of the vaginal wall by needle 21A a cut having first been made in said wall, and also penetration of the soft tissue at one side of urethra 30, the needle then according to Fig. 5 being passed close to the back of the pubic bone 31 and then through the abdominal wall above the pubic bone. A cut can be done through the abdominal wall for the passage of the needle therethrough but if the needle is pointed it may be
20 sufficient to let the needle penetrate into the abdominal wall from the inside thereof and to make a registering cut in the abdominal wall on the outside thereof.

25 The shank of the instrument is now disconnected from needle 21A, Fig. 6, by rotating shaft 15 at knob 16 so that the threaded portion 18 of the shaft is unscrewed from the threaded portion 23 in needle 21A said needle then being withdrawn from the abdominal wall by means of forceps and tape 26 being pulled into and through the tissue as illustrated in Fig. 7.

30 The other needle 21B is now attached to the shank, Fig. 8, and is passed through a cut in the vaginal wall to pass through the soft tissue at the other side of urethra 30. Needle 21B is passed through the abdominal wall, Fig. 9, and then, after having been disconnected from the shank, is
35 withdrawn from the abdominal wall, Fig. 10, all in the same way as in the earlier procedure with needle 21A.

Tape 26 is now located at each side of urethra 30 as shown in Fig. 10 and is tightened with the loop formed by the tape located on the inside surface of the vaginal wall, Fig. 11. The surplus of the tape at the outside of the abdominal wall is cut off. Then, the tape is left as an implant in the body to form an artificial ligament attached to the abdominal wall and providing the support for urethra as required in order to restore the urinary continence.

Another kind of tape which may be used in the method according to the invention can be more closely woven than the tape mentioned above and can be of such material that the tape after a shorter or longer period will be completely resorbed. By the development of fibroblast proliferation stimulated by the tape the reinforcement of the tissue required in order to restore the urinary continence will be obtained.

2198778

1/8

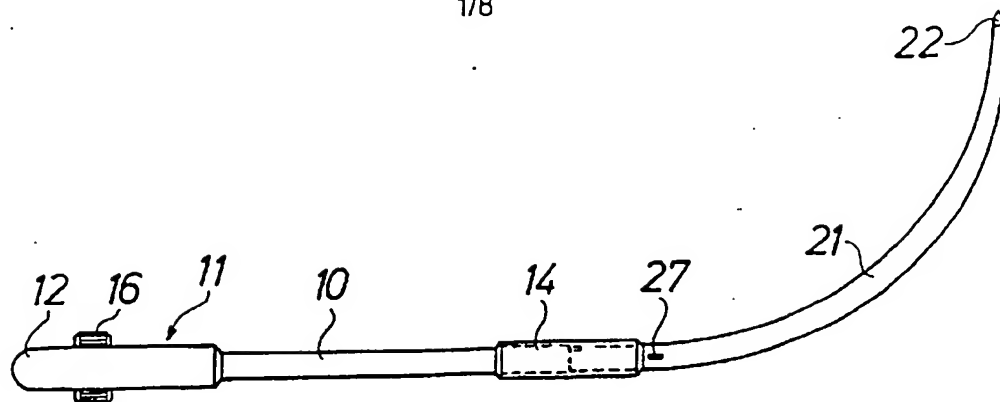


FIG. 1

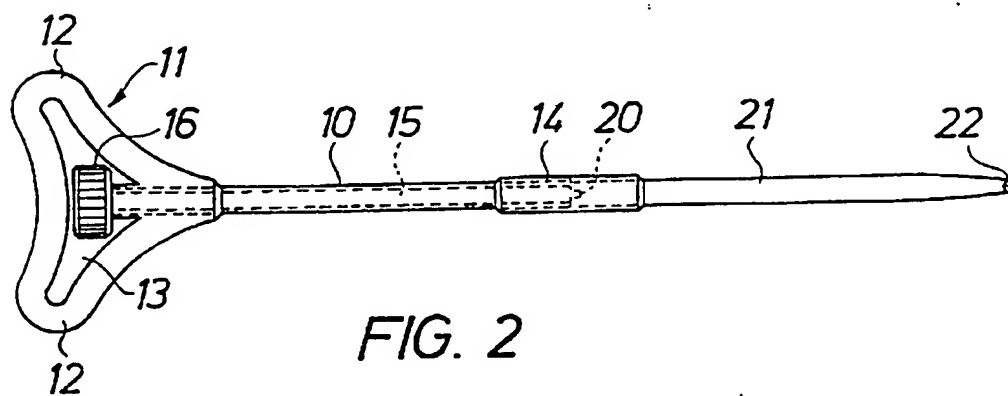


FIG. 2

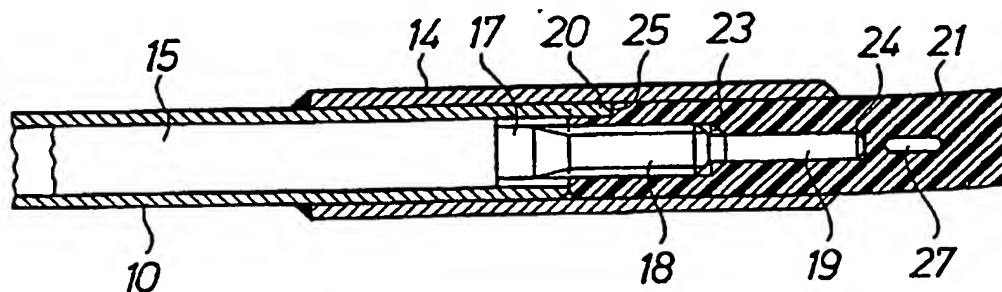


FIG. 3

SUBSTITUTE SHEET

2/8

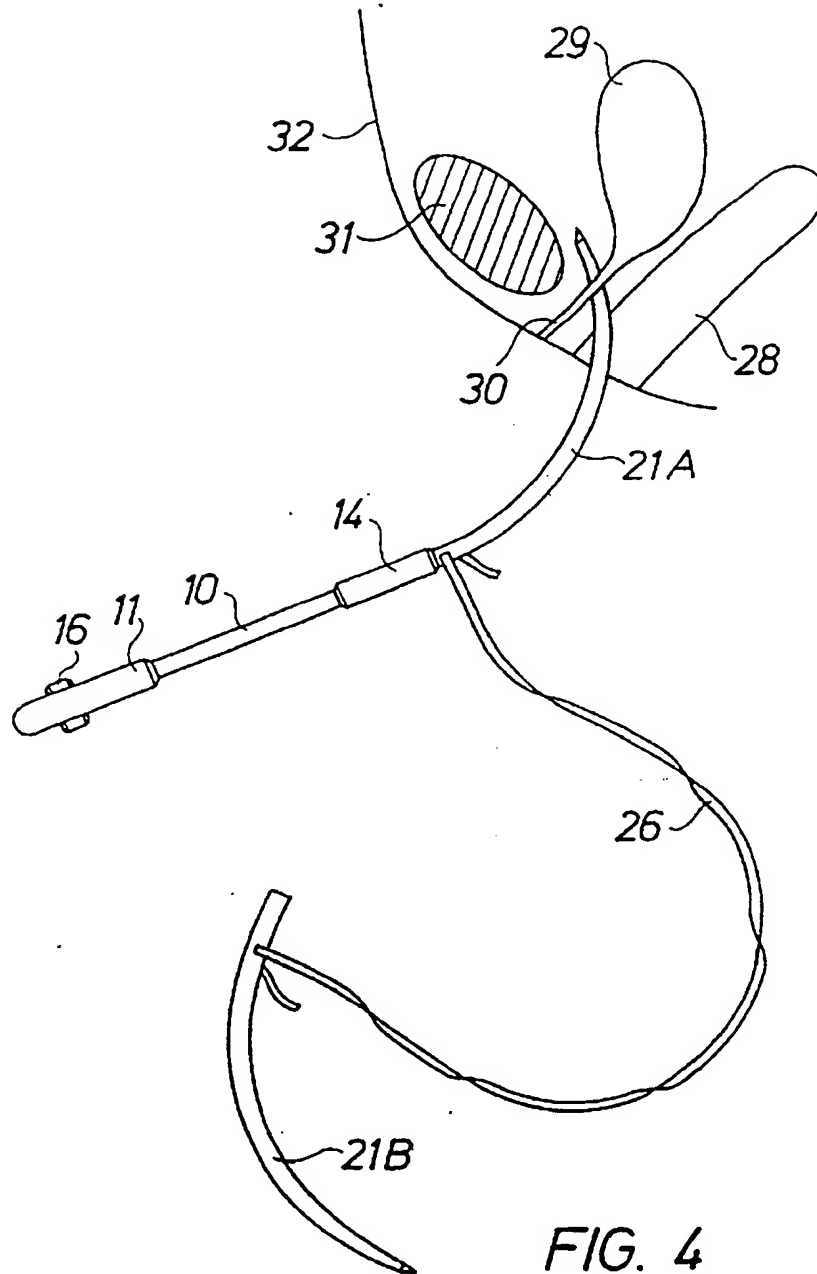


FIG. 4

3/8

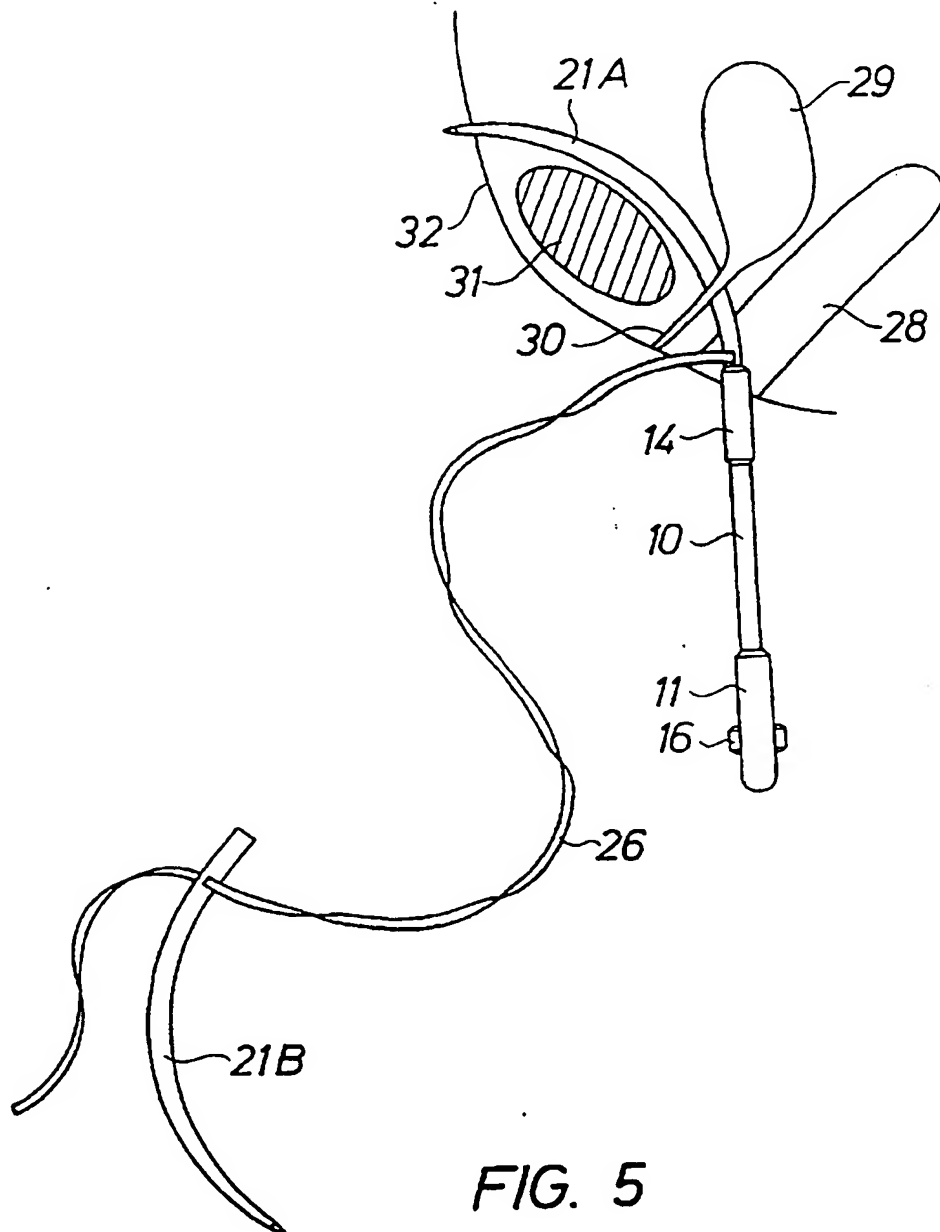
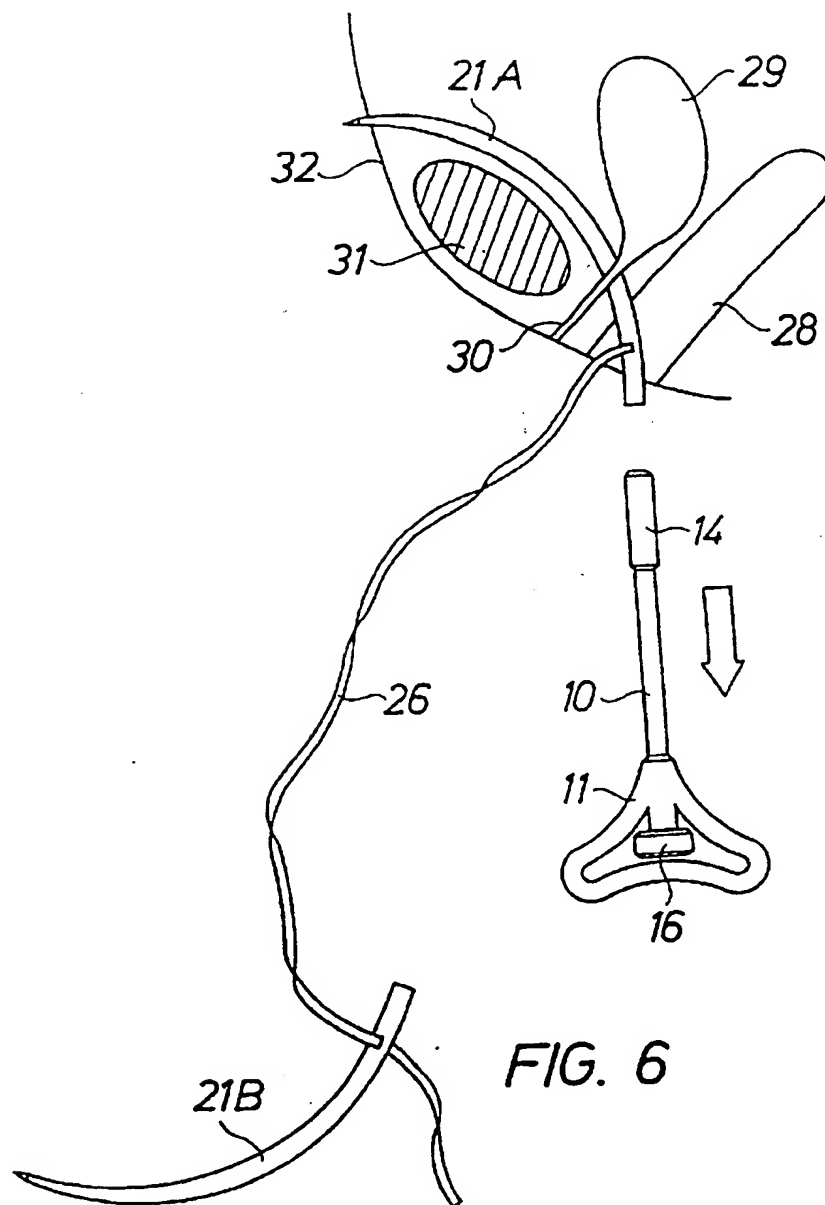


FIG. 5

4/8



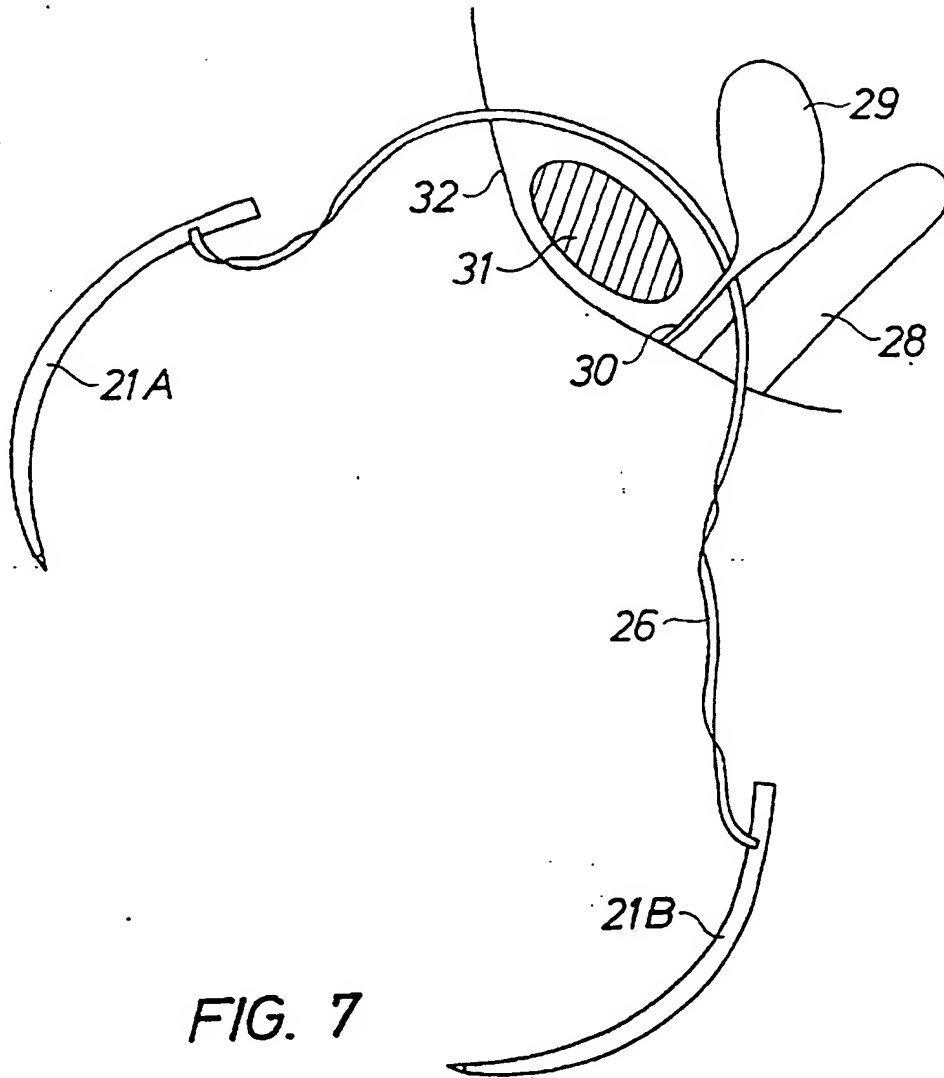


FIG. 7

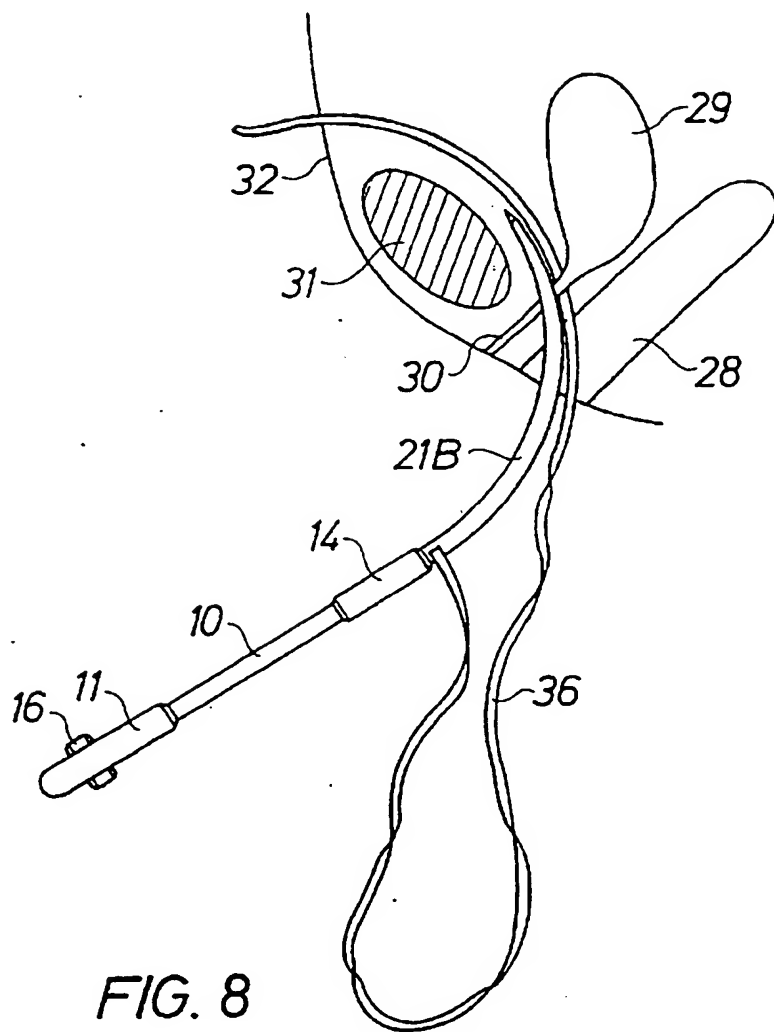


FIG. 8

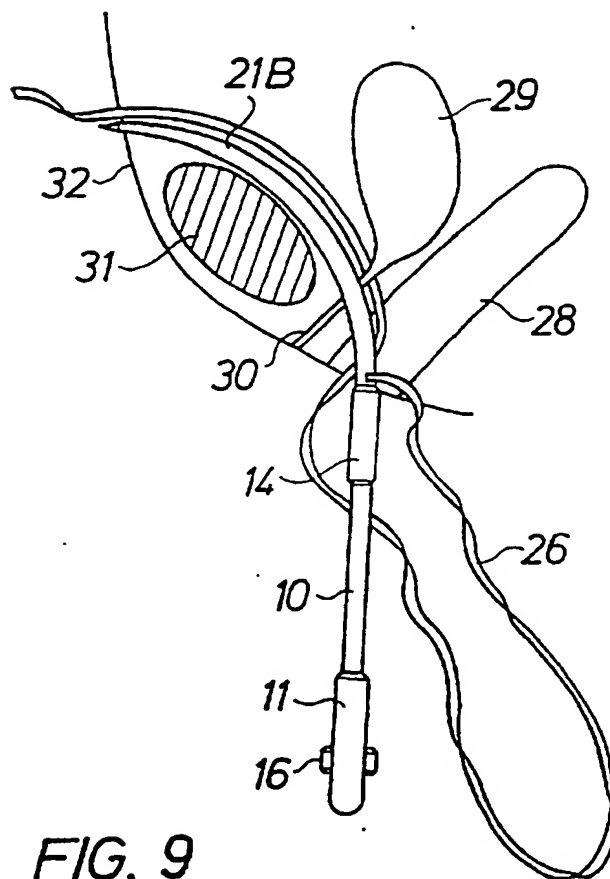


FIG. 9

8/8

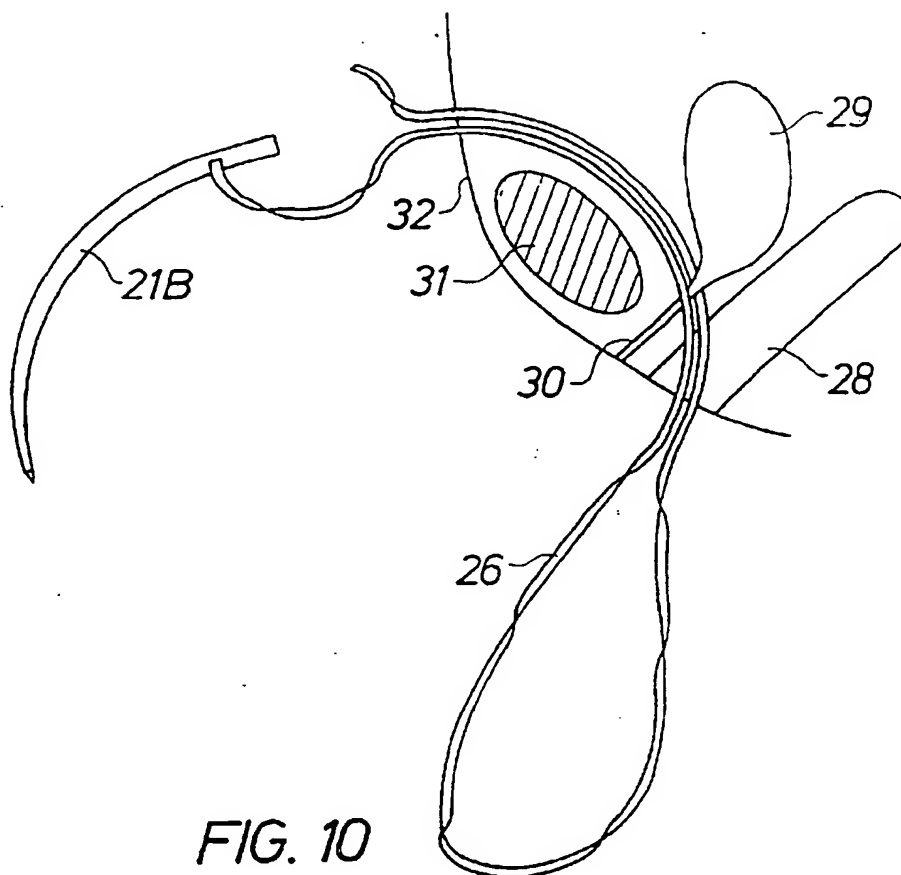


FIG. 10

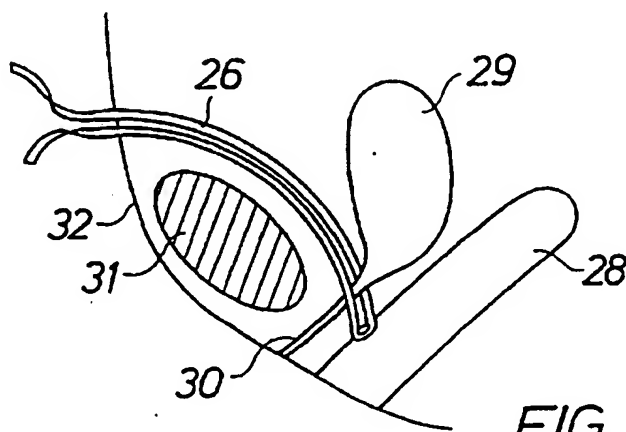
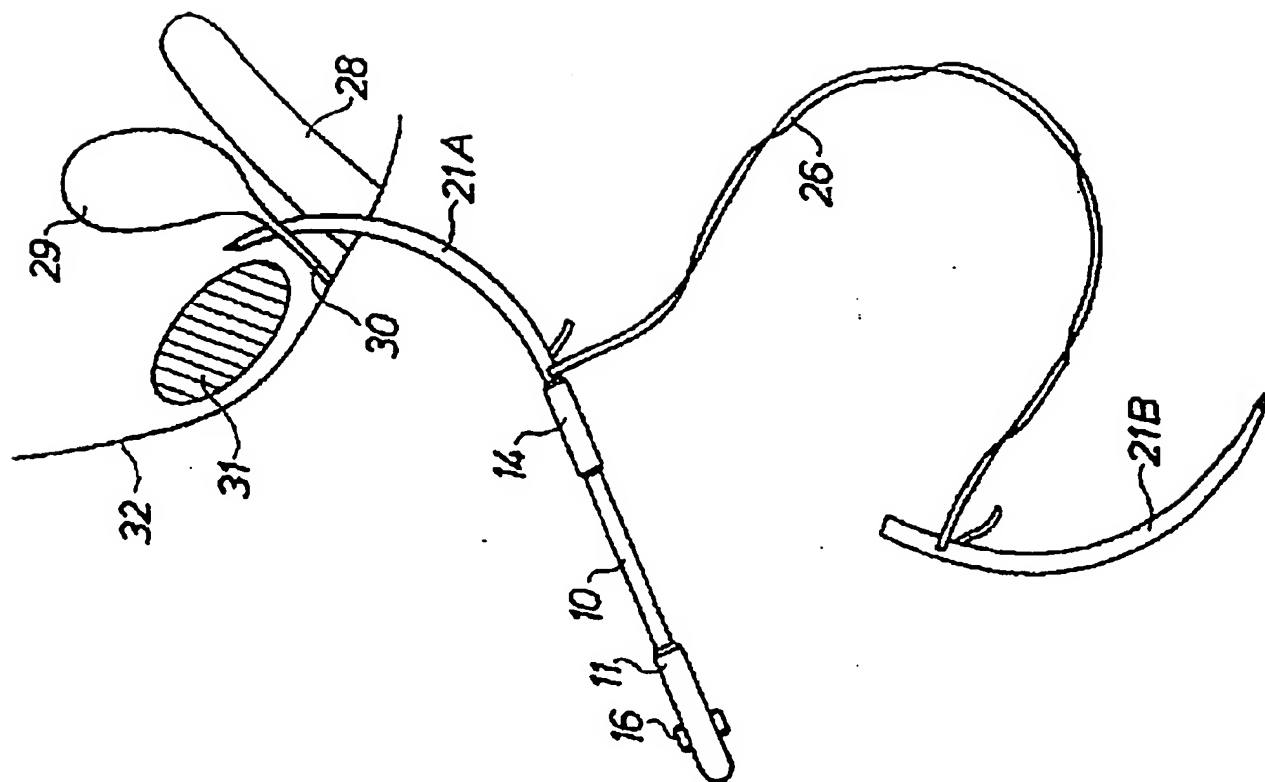
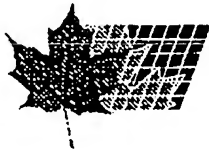
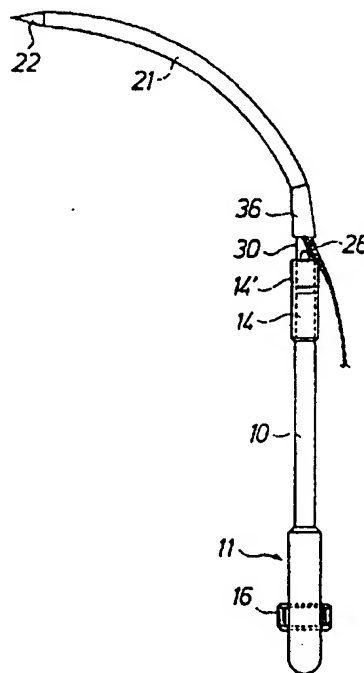


FIG. 11





(72) ULMSTEN, Ulf, SE
(71) MEDSCAND MEDICAL AB, SE
(51) Int.Cl.⁶ A61B 17/04
(30) 1995/10/09 (9503512-7) SE
(54) **INSTRUMENT CHIRURGICAL DE TRAITEMENT DE
L'INCONTINENCE URINAIRE CHEZ LA FEMME**
(54) **SURGICAL INSTRUMENT FOR TREATING FEMALE
URINARY INCONTINENCE**



(57) L'invention porte sur un instrument chirurgical permettant de traiter l'incontinence urinaire chez la femme comportant une tige (10) munie d'une poignée (11) placée à l'une de ses extrémités, et deux éléments incurvés (21A, 21B) en forme d'aiguille pouvant être fixés l'un après l'autre à l'autre extrémité de la tige de manière à la prolonger par une extrémité incurvée et attachés ensemble par un treillis (26) recouvert d'une mince gaine (34) de plastique fixé sur chacun d'eux à une extrémité et s'implantant dans le corps de la patiente.

(57) A surgical instrument for treating female urinary incontinence comprises a shank (10) having a handle (11) at one end thereof, and two curved needle-like elements (21A, 21B) which can be connected one at the time with the shank at the other end thereof to form a curved end portion of the shank and are attached at one end thereof each with one end of a netting (26) which is intended to be implanted into the body and is covered by a thin plastic sheath (34).